STANDARD OPERATING PROCEDURE (SOP)

TITLE: SITE INITIATION

DO NOT USE THIS SOP WITHOUT FIRST CHECKING IT IS THE LATEST VERSION

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Applicable Clinique Research Site(s):	All

Approved By:	Roseanne Onyia Founder/Director, Clinical Operations; Clinique Research
Signature:	
Date:	January 2020

1. PURPOSE:

The purpose of this SOP is to describe the procedure of site initiation undertaken at Clinique Research and to ensure:

- All relevant parties (sponsors and sites) are consulted and can support the project.
- The proposed trials are a strategic fit and aligns with Clinique Research's core values.
- Research projects have the best possible outcome in terms of recruitment, patient safety, budget, and time frames.

2. SCOPE:

All clinical trials to be monitored and managed at Clinique Research.

3. APPLICABILITY:

This applies to all Clinique Research employees, contract staff and to all relevant external persons or parties proposing to engage in the clinical trial services at Clinique Research.

4. GLOSSARY OF TERMS:

Please refer to Clinique Research SOP Glossary of Terms (see Related Documents).

5. PROCEDURE:

Clinique Research is responsible for monitoring and managing clinical trials in accordance with ethical and regulatory standards. Site Initiation is a visit is scheduled after the study sponsor has already selected the site to participate in a clinical trial.

5.1 SITE INITIATION VISIT

- Prior to study enrollment, the assigned Study Monitor (a Clinical Research Associate, CRA of Clinique Research) on behalf of the sponsor will conduct a Site Initiation Visit (SIV) to provide the principal investigator and the study team training on the protocol, procedures, processes and monitoring plan.
- During the SIV, the CRA must make sure that the site is ready to start enrolling subjects in the clinical trial.
- The CRA makes sure that the site has all the passwords and appropriate study staff have access to the various vendor, portal platforms and EDC systems which will be used during the course of the study.
- The CRA ensures that the Investigational Product (IP) is on site.

- The CRA ensures management and accountability of IP utilizing an investigational product accountability log.
- Review instruction on study-specific activities such as diagnostic tests, lab kits or study-required software and any related recordkeeping requirements (e.g., temperature logs, calibration logs, etc.).
- The CRA confirms that all the source documents and regulatory documents are completed. In addition, the CRA checks for informed consent documents and confirms that the site has Institutional Review Board (IRB) approval.
- The CRA checks for lab kits and essentially all materials and equipment that the site will need to start screening subjects for the trial, including answering the Principal Investigator (PI) questions on any protocol related matters.
- A SIV Checklist is available for use and contains the information required to be reviewed and discussed.
- The CRA confirms method for Adverse Event/Serious Adverse Event reporting.
- The CRA ensures proper data collection and record keeping.

6. VERSION CONTROL:

Document History	
Version	**Summary of Changes**
1.0	N/A – First Issue

7. APPENDIX:

Site Initiation Visit Checklist
Monitoring Visit Follow Up Letter and Table
Site Delegation Log
Temperature Monitoring Log
Monitoring Plan